



Distribution Operations Center (DOC) U.S. Army Medical Materiel Agency (USAMMA)

Cold Chain Management Briefing

Presented by

**USAMMA Pharmacy Consultant
Deputy Director for Distributions, MILVAX**

October 2006



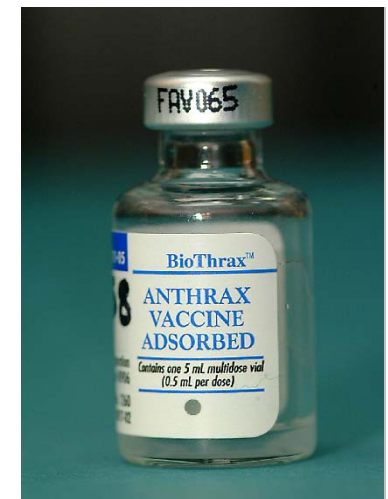
Agenda

- **Mission**
- **Vision**
- **Principal Functions**
- **Cold Chain Management:**
 - **Key Principles of Cold Chain Management/Distribution**
 - **Temperature Sensitive Medical Products Management**
 - **Equipment used to support Cold Chain Distribution**
- **Anthrax, Smallpox and Influenza Vaccines:**
 - **Ordering Process**
 - **Approval Process**
 - **Inventories**
 - **Disposition**



Mission

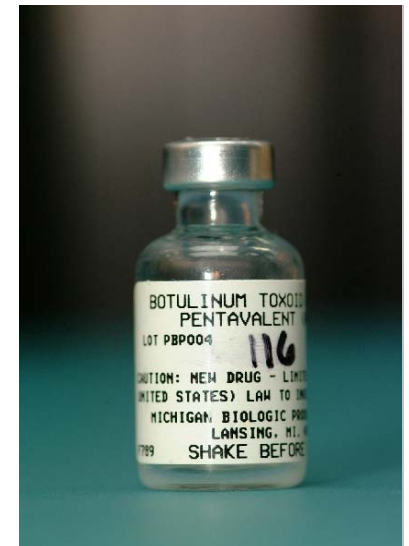
➤ We have the exclusive distribution management mission for the Department of Defense (DoD) of Anthrax and Smallpox vaccines to include other temperature sensitive medical Products (TSMPs). Additionally, we provide consultation and training on Cold Chain Management principles and procedures.





Vision

- To develop state of the art distribution mechanisms for temperature sensitive medical products in support of DoD objectives and to educate internal and external customers on the proper storage, receipt and distribution of these products.





Historical Perspective

- Inception and development of cold chain management principles created as a result of **FREEZING** loss of 200,000 doses of anthrax vaccine in 1998, **ICE IS BAD**
- 80% of vaccine/product loss and suspensions are due to **FREEZING**
- Comparison of military procedures with civilian; World Health Organization believes 50% of vaccine is temperature compromised



Principal Functions of USAMMA/DOC Personnel

- Accountability
- Ordering Procedures
- Education
- Visibility
- Order Fulfillment
- Escorts
- Real Time Tracking (Commercial Carriers)
- Prioritized Redistribution - Cross-leveling



What is Cold Chain Management?

➤ Cold Chain Management is the process of preparing temperature sensitive medical products for shipment utilizing approved systems and procedures. This includes ensuring that required temperatures are maintained throughout the supply chain and validating that those conditions are met during all phases of distribution until issue or administration.





Why Cold Chain Management is Important?

- **Assures Leadership, Service members and DoD beneficiaries that vaccine/product is safe to use and fully effective**
- **Minimize waste/Saves thousands of tax payers dollars**
 - Prevents vaccine from being compromised
 - Assures vaccine maximum shelf life and suitability for use by minimizing the rate of deterioration
 - Some vaccines are in critically short supply



US Pharmacopoeia (USP) Temperature Standards

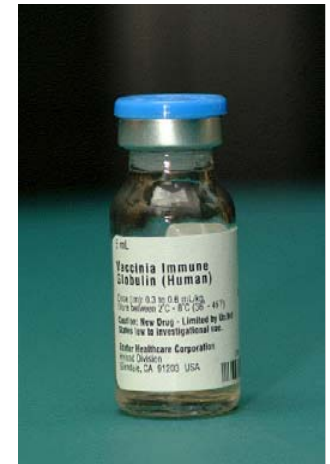
- **Refrigerated Storage** - Thermostatically controlled from 2°C to 8°C;
approximately 36°F to 46°F

- **Frozen Storage** – Thermostatically controlled from -20°C to -10°C;
approximately -4°F to 14°F



Key Principles of Cold Chain Management/Distribution

- Use of Validated Shipping Containers to keep products chilled at proper temperature, yet prevent **FREEZING**
- Inclusion of Temperature Monitoring Devices
- Rapid Movement of products - Partnership with Commercial Carrier Guarantees Express Delivery and asset visibility until delivery is completed
- Involvement with knowledgeable Customers





Safeguards that can be Implemented to Protect TSMPs

- Training
- Cooperation need with multiple disciplines
- Proper temperature monitoring
- Manual Checks and audible temperature alarm systems on a 24-hour basis
- SRP sites should have minimal stocks
- Alternate backup power for refers/freezers
- Proper labeling of refers/freezers
- Split stocks if possible
- Rotate stocks



Safeguards that can be Implemented to Protect TSMPs cont...

- **Standard Operating Procedures (SOP) must be developed with contact information for the following:**
 - Logistics, Pharmacy, Provost Marshal and Medical Maintenance personnel
 - Refrigerator repair technicians
 - Back-up storage areas
 - Temperature alarm repair technician
 - Dry Ice vendors
 - Emergency repair companies
 - Vaccine Manufacturers



Equipment Used to Support CCM

- **Validated shipping containers/boxes**
- **Temperature monitoring devices**
- **Gel packs (coolants/refrigerants)**
- **Packing Protocols**
- **Audible alarms**



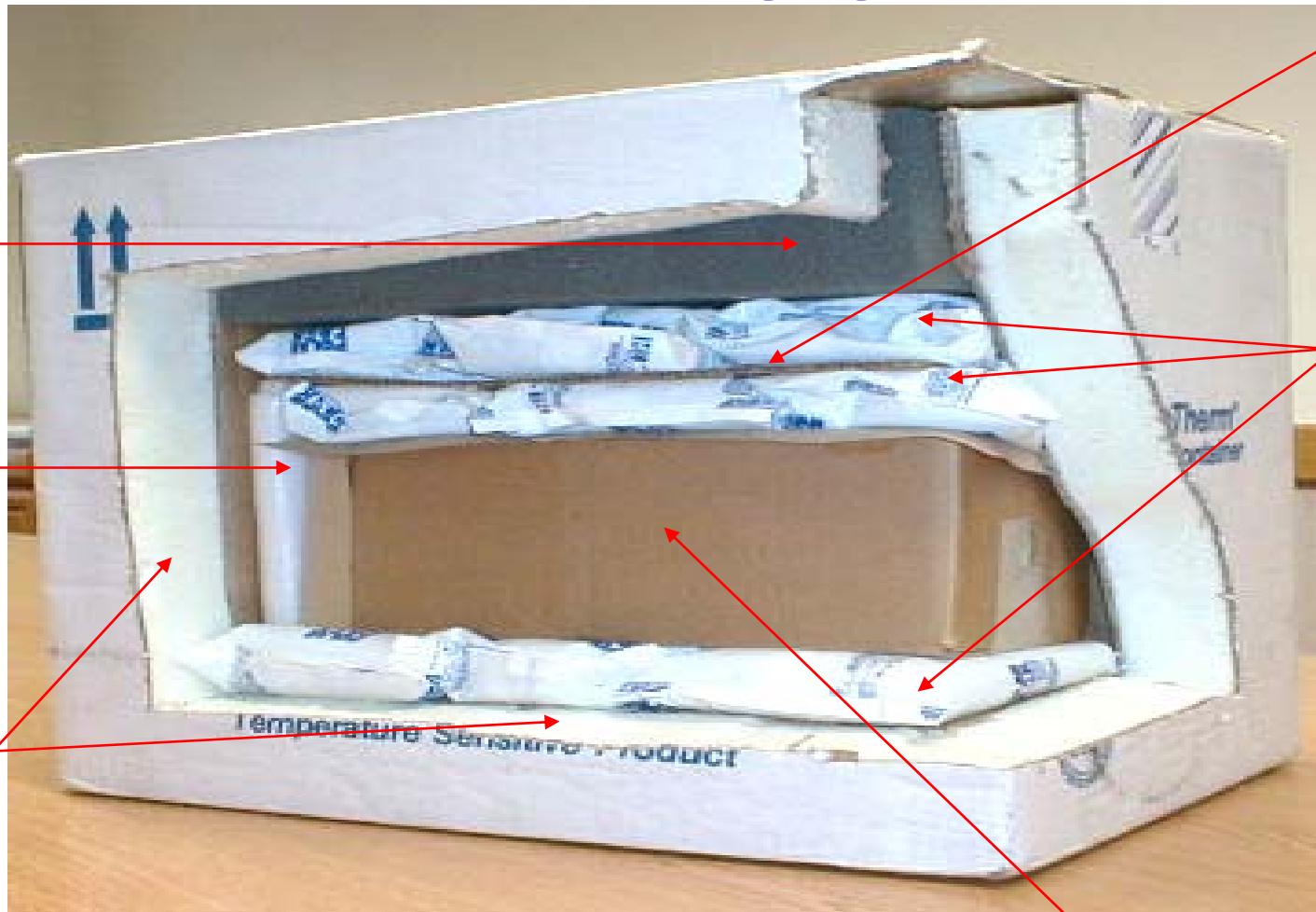
Endurotherm Boxes



**Validated shipping containers and packing protocols
assures product safety and efficacy**



Endurotherm Insulated Shipping Containers Packaging



Fiberboard Barrier

Gel Packs

Product and TempTale Temperature Monitor inside the fiberboard box



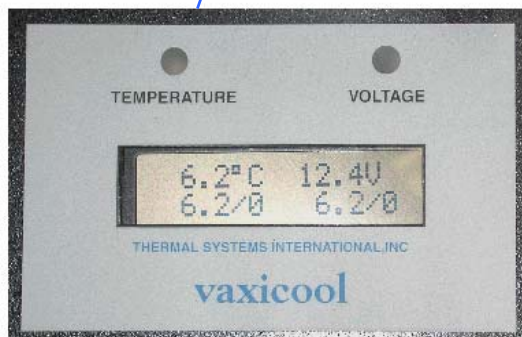
VaxiCool Dual Mode Container



THE SYSTEM IS COMPRISED OF:
a) A SUPER-EFFICIENT COMPRESSOR,
b) A SUPER INSULATED CONTAINER USING VACUPANEL INSULATION DESIGNED TO MAINTAIN VACCINES AT APPROPRIATE TEMPRATURE BETWEEN 2-8 CELSIUS.

BATTERY BOX CONTAINS
(2) 12 VOLT/20 AMPS
DRY GEL-CELL BATTERIES.

POWER PANEL CONTAINS SOLAR INPUT
PLUG, AC POWER FROM 90-270 VOLTS.



LCD SCREEN DISPLAYS THE TEMPERATURE
AND BATTERY VOLTAGE.



VAXICOOL HAS AN INSIDE DIMENSION OF 14 (LENGTH)
BY 10-1/2 (WIDTH) BY 10 (DEPTH) ITS PAYLOAD



VaxiPac Shipping Container

VaxiPac is used for transport of small quantities of refrigerated products



**EXTERIOR DIMENSION OF
15 (LENGTH) BY 7.75
(WIDTH) BY 11.38 (DEPTH)**



**WALLS LINED WITH
VACUPANEL INSULATION**

**VAXISAFE IS A PHASE
CHANGE MATERIEL
(PCM) THAT STARTS TO
HARDEN OR FREEZE AT
6 CELSIUS.**





Temperature Monitors

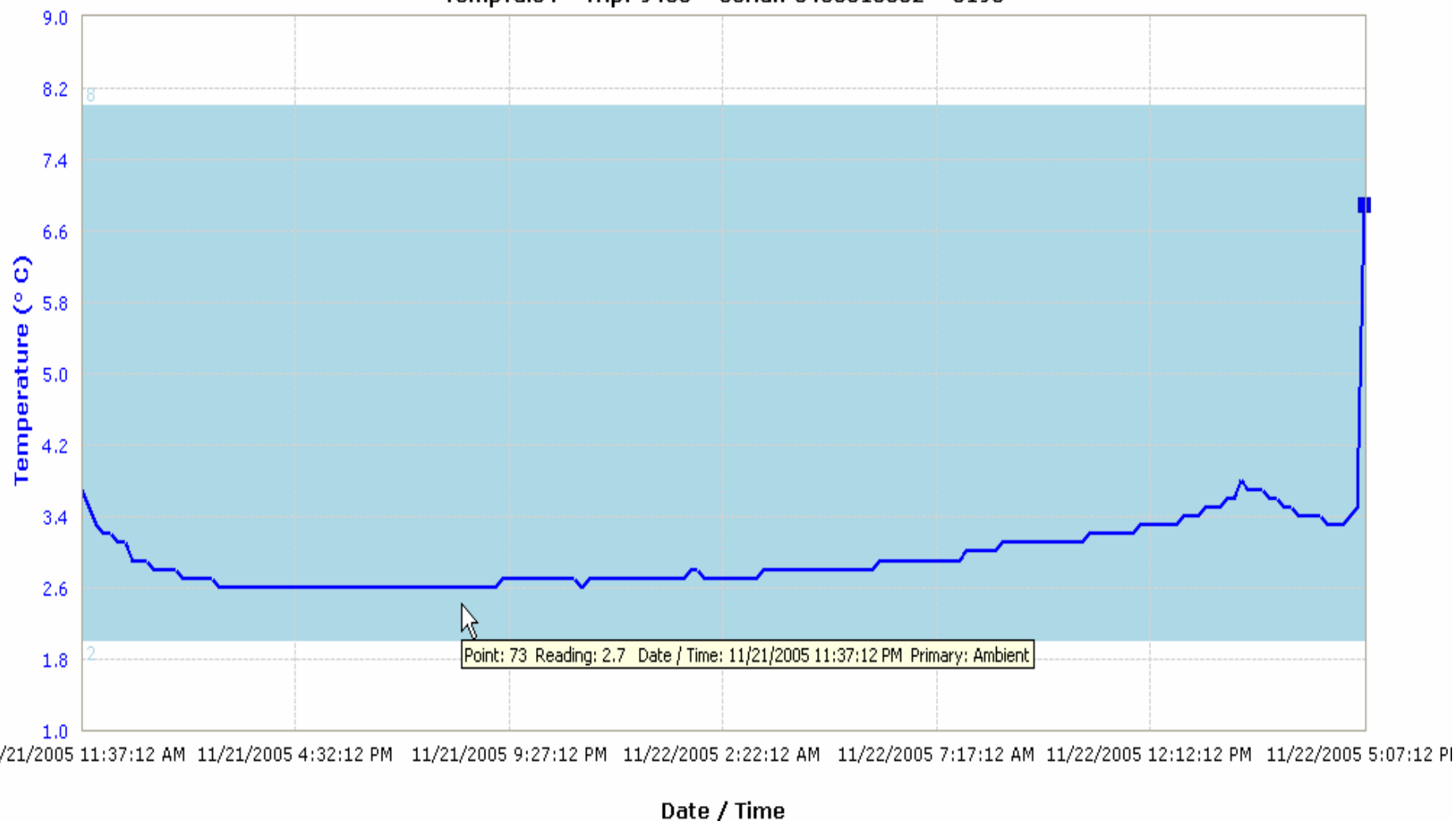


Primary Operating Range	-22°F to +158°F (-30°C to +70°C)
Primary Sensor Options	Ambient Temperature only
Primary Sensor Accuracy	$\pm 2^{\circ}\text{F}$ from -22°F to 0°F ($\pm 1^{\circ}\text{C}$ From -30°C to -18°C) $\pm 1^{\circ}\text{F}$ from 0°F to +122°F ($\pm 0.5^{\circ}\text{C}$ from -18°C to +50°C) $\pm 2^{\circ}\text{F}$ from +122°F to +158°F ($\pm 1^{\circ}\text{C}$ from +50°C to +70°C)
Memory Size	1,920 Data Points
Temperature Alarms	LCD Alarm for single event or cumulative time out of range
Start-Up Delay	Minimum - 0 Seconds Maximum - 194 Days
Measurement Interval	Minimum - 10 Seconds Maximum - 2 Hours
Primary Sensor Resolution	0.1° (1/10°)



TempTale Download Data

TempTale4 Trip: 9438 Serial: 3408516032 - 3198





Packing Protocols

The following packing protocols were developed to ensure maximum protection for temperature sensitive medical products requiring storage temperatures between 2°C and 8°C (36°F and 46°F) during distribution:

Cold weather: Is used when ambient temperature at the receiving site consistently remains below 55°F. All gel packs used are refrigerated or chilled to +4°C.

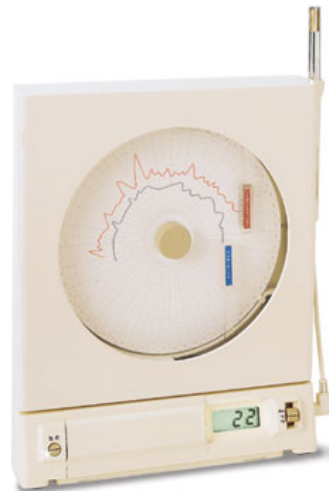
Moderate weather: Is used when ambient temperature at the receiving site is between 55°F and 77°F. Uses a combination of chilled and frozen gel packs.

Warm weather: Is used when ambient temperature at the receiving site is consistently above 77°F. Uses a combination of chilled and frozen gel packs.

NOTE: Packing protocols are designed to hold 2°C to 8°C for at least 72 hours or longer.



Temperature Recorders with Remote Monitoring and Audible Alarms





Anthrax and Smallpox Vaccines Ordering Process

- **Customers must register on line (USAMMA/DOC secured website) and create own log-in and password:**
 - DOC personnel and local Service POCs validate registration
 - DOC personnel enables customer in our DOC's secure server
 - Customer receives authorization to access our secure webpage via email



Approval Process

Army:

301-619-4318 - Validate
301-619-4307 - Approving Officer

Navy/Marines: - NAVMEDLOGCOM

301-619-8054 - Validate (Navy and Marines)
202-762-3437 - Approving Officer (Navy)
703-955-1405- Approving Official (Marines)

Air Force: - AFMSA

301-619-4170 - Validate
202-767-4216 - Approving Officer (Active Duty)
301-836-7255 - Approving Officer (ANG)
478-327-1478 - Approving Officer (Air Reserves)

Coast Guard:

202-267-2622 – Validation and Approving Officer



Vaccine Inventory

- **DoD activities are required for reporting a monthly inventory of the anthrax and smallpox vaccine (Reference DOD-MMQC-04-1143)**
- **Inventory Requirements:**
 - Logistics Activities and customers are required to report their physical inventories by the first Friday of each month to their major commands
 - Major Commands are required to report their physical inventories by the second Friday of each month to USAMMA/DOC
 - **Vaccine Reports must include:**
 - Number of unopened vials and kits by lot number





I suspect the vaccine is compromised What do I do?

➤ I will:

- Contact USAMMA – Do not contact the Manufacturer
- Prepare Executive Summary (EXSUM)
- Destroy the vaccine if necessary (After consulting USAMMA)

➤ Causes that may compromise your vaccine:

- Power Failure
- Refer/freezer malfunctions
- Vaccine sitting out of the refrigerator for extended period of time/improper storage of vaccine
- Shipping mis-sort/frustrated cargo





Executive Summary (EXSUM)

- DoD Activities are responsible for reporting any loss of Anthrax, Smallpox and Flu Vaccine, due to expiration, or loss of efficacy by another means
- EXSUM submitted in Memorandum Format
- EXSUM should be routed up the chain of command for review and endorsement before faxing/emailing to USAMMA/DOC
- USAMMA/DOC must receive the EXSUM from activities before replacement of vaccine will be shipped




Vaccine Disposal

- DoD activities are responsible for disposal of compromised or expired vaccine
- Destruction memorandum should be routed up the chain of command for review and endorsement before faxing to USAMMA/DOC
- Methods of destruction:
 - AVA/FluZone/FLUMIST: can be disposed in sharps container, autoclaved, incinerated, or use a returns program
 - Smallpox: **DO NOT DISPOSE OF SMA VACCINE (DRYVAX) UNLESS DIRECTED VIA A MEDICAL MATERIEL QUALITY CONTROL MESSAGE (MMQC)**
 - Vaccine vials can be dropped into the hospital sharps container, autoclaved, or disposed of following the procedure for all other biohazard materials
- AVA, SMA and Flu disposition instructions available at:
<http://www.usamma.army.mil/vaccines/anthrax/antxhome.htm>
Destruction Codes can be found on the USACHPPM website:
<http://chppm-www.apgea.army.mil>






USAMMA Website



USAMMA

U.S. ARMY MEDICAL MATERIEL AGENCY - FORT DETRICK, MARYLAND



Quick Links

Home

About Us

Products & Services

Reference

FAQ


Search

GO


The USAMMA Mission

To provide medical materiel lifecycle management and logistics solutions to the Warfighter across the full spectrum of healthcare missions worldwide.


SEMPER RESPONSUS, in relentless pursuit of medical readiness!




HOT TOPICS



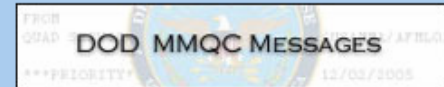
USAMMA IN THE NEWS



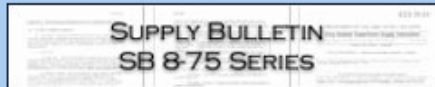
USAMMA CDROM NOW AVAILABLE




MEDICAL EQUIPMENT LITERATURE CDs




DOD MMQC MESSAGES



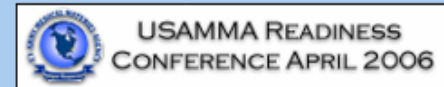
SUPPLY BULLETIN SB 8-75 SERIES



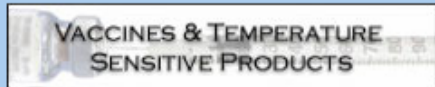
MEDICAL SERVICES INFORMATION LOGISTICS SYSTEMS (MEDSILS)




CHEMICAL DEFENSE MATERIEL (SB 8-75-S7)



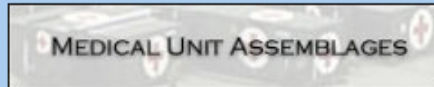
USAMMA READINESS CONFERENCE APRIL 2006



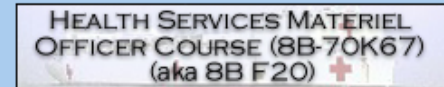
VACCINES & TEMPERATURE SENSITIVE PRODUCTS




NEW COMBAT LIFESAVER BAG




MEDICAL UNIT ASSEMBLAGES




HEALTH SERVICES MATERIEL OFFICER COURSE (8B-70K67) (aka 8B F20)



MEDICAL LOGISTICS AGENCIES HOST VENDOR DAYS 2006



LOGISTICS ASSISTANCE PROGRAM CUSTOMERS NEEDS SURVEY



ICE INTERACTIVE CUSTOMER EVALUATION

Contact USAMMA

External Links Disclaimer


Privacy & Security Notice

www.usamma.army.mil




Distribution Operations Center Links





USAMMA

U.S. ARMY MEDICAL MATERIEL AGENCY - FORT DETRICK, MARYLAND



Quick Links

Home

About Us

Products & Services

Reference

FAQ

Search

GO

Vaccines & Temperature Sensitive Products

Anthrax Vaccine Immunization Program

Cold Chain Management Processes and Procedures for all Medical Temperature Sensitive Products

Influenza Virus Vaccines (Flu) Program

Smallpox Vaccination Program

Contact USAMMA

External Links Disclaimer

Privacy & Security Notice

This page was last modified on : 08/21/2006

<http://www.usamma.army.mil/vaccines/vaccines.cfm>



Cold Chain Management Links



USAMMA

U.S. ARMY MEDICAL MATERIEL AGENCY - FORT DETRICK, MARYLAND

[Quick Links](#)

[Home](#) [About Us](#) [Products & Services](#) [Reference](#) [FAQ](#)

Cold Chain Management Processes and Procedures for all Medical Temperature Sensitive Products

- [Packing Protocols](#)
- [Equipment Used to Support Cold Chain Distribution](#)
- [Equipment Source Information](#) (Equipment sources used by USAMMA-DOC)
 - [Endurotherm Boxes \(Insulating Shipping Containers\)](#)
 - [Polar Packs \(Refrigerant\)](#)
 - [Temperature Monitors](#)
 - [VaxiCool and VaxiPac](#)
- [Cold Chain Management Briefing](#)
- [Guidelines for Maintaining and Managing the Vaccine Cold Chain](#) [External Link]
- [Cold Chain Management Education CDROM](#)
 - [CCM CDROM Welcome Message](#)
 - [CCM CDROM Index](#)
 - [CCM CDROM Order Form](#)
 - [CCM Video Download](#)
- [Cold Chain Management Video CDROM NOW AVAILABLE](#) for [Downloading](#) and [Ordering](#)
- [Safeguarding Medical Materiel Assets](#) (LTG Kevin C. Kiley 12 Jan 05 Memorandum Directive)
- [Operations Management Bulletin No. 01-05](#) (Monitoring Temperatures on Refrigerator/Freezer Units Storing Temperature Sensitive Medical Products)

[Contact USAMMA](#) [External Links Disclaimer](#) [Privacy & Security Notice](#)

http://www.usamma.army.mil/vaccines/CCM/Cold_chain_management.cfm



MMQC Messages Registration Site





USAMMA

U.S. ARMY MEDICAL MATERIEL AGENCY - FORT DETRICK, MARYLAND



Quick Links	Home	About Us	Products & Services	Reference	FAQ	Search	GO
-------------	------	----------	---------------------	-----------	-----	--------	----



Department of Defense Medical Materiel Quality Control Messages (MMQC)

- [DOD Immediate MMQC Message Receipt Acknowledgement](#)
- [Subscribe to MMQC Messages here](#)

Choose search method from the list below. A [description](#) of each message type is available.

- [DOD-MMQC Messages](#) (June 97 to Present)
- [Army MMI Messages](#)
- [Vaccine Messages](#)

[Contact USAMMA](#)[External Links Disclaimer](#)[Privacy & Security Notice](#)

http://www.usamma.army.mil/apps/nala_qaweb/nala_index.cfm



USAMMA/DOC POC's

USAMMA Pharmacist Consultant and MILVAX Deputy Director, Distribution Operations
(301) 619-4307

Project Manager

(301) 619-1197 or (301) 676-0857 (Cell)

Functional Analyst/Web Support

(301) 619-4121 or (301) 676-2017 (Cell)

Operations Manager

(301) 619-4318 or **(301)-676-1184 (After duty Cell)**

Flu Program Manager

(301) 619-3242

Distribution Specialists

(301) 619-3017/7913/4128

Financial Specialist

(301) 619-4411

Operations Administration Specialist

(301) 619-7235

Website registration/Technical Support

(301) 619-4320

Support Administration Specialist

(301) 619-4198

MMQC Messages

(301) 619-4300

